Preliminary Guidance on Pregabalin (Lyrica™)

VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

Dear VISN Formulary Leaders,

Pregabalin (Lyrica, Pfizer) capsules c-v became available for use on September 21, 2005. The PBM SHG expects that the NME monograph and criteria for pregabalin will be ready for initial review in late November to early December. As requested by the PBM SHG, Pfizer has provided an AMCP dossier on this agent and has agreed to do pharmacoeconomic analyses of pregabalin using VA cost data.

Until the PBM SHG has had a chance to evaluate this drug for safety, efficacy, and cost-effectiveness and to complete the national criteria, we STRONGLY suggest that you

- adhere to the NONFORMULARY request procedures for this nonformulary drug;
- **only provide for the FDA-approved indications** (specifically, only for painful diabetic neuropathy, postherpetic neuralgia, and adjunctive treatment of partial onset seizures in adults);
- use pregabalin conservatively for the FDA-approved indications (e.g., after other evidence-based modalities have been tried); and
- note that pregabalin is a schedule V controlled substance (because of reports of euphoria).

Pregabalin should remain nonformulary at the VISN level prior to the national NME review.

The PBM SHG appreciates your cooperation and patience as it makes a thorough review of this agent.